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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/485,193 | 12/27/2000 | Patrick A. Schneider | 018002-00101 | 1634 |

7590 01/29/2003

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| EXAMINER |
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ZITOMER, STEPHANIE W

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| ART UNIT | PAPER NUMBER |
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1634

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DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/485,193

Applicant(s)
SCHNEIDER et al.

Examiner
S. Zitomer

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1634



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 15, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above, claim(s) 33-75 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-12 and 14-32 is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5, 13
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

New examiner

1. The examiner in charge of prosecuting this application has changed. The new examiner is Stephanie Zitomer.

Election

2. Applicant's election with traverse of Group I, claims 1-32, in Paper No. 17 filed November 4, 2002, is acknowledged. The traversal is on the ground(s) that applicant believes Groups I and III should be examined together because the restriction requirement fails to support restriction according to USPTO practice as set forth in MPEP 803. This is not found persuasive because the application was filed under 35 U.S.C. 371 and is therefore subject to Lack of Unity practice as in PCT applications. See MPEP 1875 *et seq.* The Lack of Unity restriction set forth in paper no. 12 mailed February 26, 2002 is proper under PCT Rules 13.1 and 13.2 with regard to a special technical feature that was known in the art and wherein the methods protocols were also known in the art. The Lack of Unity requirement is still deemed proper and is therefore made **FINAL**. Accordingly, claims 33-56 are withdrawn from prosecution as being drawn to nonelected inventions.

Defective oath/declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Priority information

4. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). Applicant must state that the application is filed under 371.

Rejection under 35 U.S.C. 112, second paragraph: Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim lacks antecedent basis in claim 9 for "the immobilized polynucleotide" because claim 9 recites immobilization of the prothymosin mRNA or cDNA" and not the polynucleotide. Furthermore, it is unclear how an array of polynucleotides can be used in an *in situ* assay wherein the polynucleotide must be free in solution to contact the fixed tissue.

Prior art

6. No prior art has been found that would provide grounds for rejection under 35 U.S.C. 102 or 103. The closest prior art includes the patent to Puente (5,248,591) which teaches that prothymosin alpha expression was known to be associated with cell division such that prothymosin alpha could be used as a cell proliferation marker. Puente discloses a radioimmunoassay for prothymosin alpha, which is essentially the same as that of applicant's claims 23-26 and 28, employing an antibody to a prothymosin alpha peptide earlier reported in the art and applied it to identifying breast cancer tumors that were likely to recur after surgical removal or to metastasize based on the significantly higher prothymosin expression level in cancer tissue over normal tissue from the same patient. Oikawa et al. (*Endocrinol.* 1990, applicant's reference AI) discloses the nucleotide and deduced amino acid sequences of prothymosin- α found in human ovary, placenta and other organ tissues. Sburlati et al. (*PNAS USA* 1991 applicant's reference AC), although incomplete, teaches that prothymosin α mRNA and protein are present in virtually all mammalian tissues and that amounts of prothymosin α mRNA and protein are roughly proportional to the proliferative activity of the tissue in which it is measured. The endometriosis research review by Guidice et al. (*J. Reprod. Med.* 1998) reports that levels of the angiogenic factor, VEGF, which was known to be involved in the establishment of cell proliferative lesions, in peritoneal fluid in endometriosis were directly correlated with severity of the disease. The combination of these references in view of cell proliferation as

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the hallmark of endometriosis thus appears to suggest the claimed invention assays for diagnosis of endometriosis. However, it is, at best, only an invitation to try.

Conclusion

7. **Claims 1-12 and 14-32 are allowed.** This application contains claims 33-75 drawn to inventions nonelected with traverse in Paper No. 17. Applicant is reminded that nonelected claims must be canceled before the application can be allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact LIE Chantae Dessau at 703-605-1237.



Stephanie Zitomer, Ph.D.

January 27, 2003

STEPHANIE ~~W.~~ ZITOMER
PRIMARY EXAMINER